

CLAIMS

1. A pharmaceutical composition for topical administration comprising:
(i) a therapeutically safe and effective amount of lidocaine or of a
5 pharmaceutically acceptable salt thereof;
(ii) a therapeutically safe and effective amount of prilocaine or of a
pharmaceutically acceptable salt thereof; and
(iii) a therapeutically safe and effective amount of tetracaine or of a
pharmaceutically acceptable salt thereof.
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2. The pharmaceutical composition according to claim 1, further comprising
water.
3. The pharmaceutical composition according to any of the claims 1-2,
15 wherein lidocaine or its salt on the one side, and prilocaine or its salt on the
other side, form an eutectic mixture.
4. The pharmaceutical composition according to claim 3, wherein lidocaine or
its salt is in an amount from about 0.5% to about 5%, w/w, and prilocaine or
20 its salt is in an amount from about 0.5% to about 5%.
5. The pharmaceutical composition according to claim 4, wherein lidocaine or
its salt is in an amount of about 1.5%, w/w, and prilocaine or its salt is in an
amount of about 1.5%.
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6. The pharmaceutical composition according to any of the claims 3-5,
wherein tetracaine or its salt is in an amount from about 0.5% to about 8%,
w/w.
- 30 7. The pharmaceutical composition according to claim 6, wherein tetracaine
or its salt is in an amount of about 4%, w/w.
8. The pharmaceutical composition according to any of the claims 1-2, further
comprising appropriate amounts of pharmaceutically acceptable excipients to
35 constitute a topical formulation.

9. The pharmaceutical composition according to claim 8, wherein the excipients comprise at least one skin penetration enhancer.
10. The pharmaceutical composition according to claim 9, wherein the skin
5 penetration enhancer is methylpyrrolidone.
11. The pharmaceutical composition according to claim 10, wherein methylpyrrolidone is in an amount from about 5% to about 20%, w/w.
- 10 12. The pharmaceutical composition according to claim 11, wherein methylpyrrolidone is in an amount of about 10%, w/w.
13. The pharmaceutical composition according to claim 9, wherein the skin
15 penetration enhancer is dimethyl sulfoxide (DMSO).
14. The pharmaceutical composition according to claim 13, wherein dimethyl sulfoxide is in an amount from about 0.5% to about 5%, w/w.
15. The pharmaceutical composition according to claim 14, wherein dimethyl
20 sulfoxide is in an amount of about 2%, w/w.
16. The pharmaceutical composition according to claim 8, wherein the excipients comprise at least one spreading agent.
17. The pharmaceutical composition according to claim 16, wherein the
25 spreading agent is selected from hyalurodinases and derivatives of mucopolysaccharidases.
18. The pharmaceutical composition according to claim 8, wherein the
30 excipients comprise at least one viscosity increasing agent.
19. The pharmaceutical composition according to claim 18, wherein the viscosity increasing agent is selected from guar gum and a carbomer.
20. The pharmaceutical composition according to claim 18, wherein the
35 viscosity increasing agent is in an amount from about 0.5% to about 2%, w/w.

21. The pharmaceutical composition according to claim 8, wherein the excipients comprise at least one surfactant.

22. The pharmaceutical composition according to claim 21, wherein the
5 surfactant is a non-ionic surfactant.

23. The pharmaceutical composition according to claim 8, wherein the excipients comprise at least one preservative.

10 24. The pharmaceutical composition according to claim 8, wherein the topical formulation is selected from the group consisting of lotions, creams, gels, sticks, sprays, ointments and pastes.

15 25. A pharmaceutical composition for topical administration comprising the following components in the indicated approximate w/w percentages: 1.5% of lidocaine base; 1.5% of prilocaine base; 4% of tetracaine base; 10% of methylpyrrolidone; 2% of dimethyl sulfoxide; 0.08% of topical hyaluronidase; 1.5% of guar gum; 1% of Tween-20; 0.5% of Tween-80, and the necessary amount of water to 100%.

20 26. Use of a combination comprising lidocaine, prilocaine and tetracaine, any of them being as such or as a pharmaceutically acceptable salt, for the preparation of a topical anesthetic pharmaceutical composition.

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